

# BOCA RATON PSYCHIATRIC GROUP, P.A.

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March 3, 2001

Dockets Management Branch (HFA-305)  
Docket #00N-1269, Food and Drug Administration  
5530 Fishers Lane; Room 1061  
Rockville, MD 20857

Dear Sirs:

I am writing to you as a physician in private practice who would like to have some input on the new pharmaceutical labeling changes as well as other matters. I greatly appreciate your taking the time to read this letter and listen to my input. Although I am only a single physician in the community, my concerns are probably representative of many physicians like myself throughout the country. I would like to submit the following recommendations for your consideration:

1. The PDR drug description should include the following facts, laid out in a clear and easy to access manner: the drug elimination half life (perhaps also including different half lives for different age populations – child, adult, and geriatric); the route of metabolism/elimination; for drugs metabolized by the liver, the specific P450 enzyme should be delineated; if the drug induces in the other hepatic enzymes, these should be delineated.

It is very difficult to get good drug interaction information. I would hope that you are attempting to put much more information about drug interactions into the PDR. Giving the above information would be a good start. Often drug interactions are found out later after a drug is released and the information does not make it into the PDR. By knowing the specific routes of metabolism and hepatic enzymes involved, the physician could make predictions about drug interactions which have not yet been discovered.

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2. More effort should be made to have medications named in a way to assist physicians. I have been out of residency for only six years, but I am already becoming overwhelmed with all the new medications on the market. I am sure that many other physicians share the same problem. In particular, we often know the medications in our own specialty but become more and more ignorant about the other medications that our patients are taking. If the names of the medications gave us some indication of their action, learning all of the different medications would be much easier. For instance, the fact that beta blockers have generic names ending with "ol", has always been helpful. Many of the quinalones also have generic or brand names that cue you in as to their drug class. I think that all generic medication names should have an identifier as to their family class in the prefix or suffix. Additionally, the brand names should be mandated to have some similarity to the generic name so that the physician can make the association easier. A good example would be Cipro as the brand name for Ciprofloxacin. Alternatively, medication brand names could be linked to the action of the drug – as in the case of "Restoril" – a medication that promotes sleep. However, I believe that names linking classes of drugs would be preferable.

As the number of medications available continues to explode, this solution will become more and more necessary. The longer you wait, the bigger the problem will be. One might think that physicians could easily look up the names of medications to find out what they are. This is true, but when a physician is doing a consultation in the middle of a busy day, it is very easy to skip by medications in the patient's medication list that one is not familiar with. Sometimes adverse reactions and drug interactions will be missed. Please institute a name recognition program to help out the physician working busily in the field.

3. There seems to be a rule that when a physician writes an article or gives a lecture, his or her affiliation to pharmaceutical companies is listed at the end of the paper. This is helpful information. It would be ever more helpful if, in addition to listing any affiliations to pharmaceutical companies, they listed the pertinent medications produced by that pharmaceutical company. For example, in an article about depression, it might say, "Dr. Jones has received money for lectures from Lilly, the maker of Prozac".
4. We need a better source of information about drug interactions. This is a very important problem area within medical practice today. Sometimes the problem arises when physicians do not bother to check a medication list or think about drug interactions. But even after reasonable efforts, drug interactions can be missed. For instance, looking up medications in the PDR or in an article about drug interactions clipped out from a journal, could still leave you missing an important

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interaction. It seems that our knowledge about drug interactions grows every month. I believe that an excellent solution would be to create an FDA sponsored drug interaction website on the Internet. The site should be set up in such a way that a physician could merely enter a patient's medication list into the computer and the computer would spit out all of the relevant drug interactions. This computer program should be run by experts throughout the country and updated on a monthly basis. A top notch, reliable resource such as this would be invaluable to physicians and have a dramatic effect on improving healthcare at a relatively minimal cost. Perhaps the site could be funded by contributions (mandated?) from pharmaceutical companies. Alternatively, it could be funded by advertisements on the website by pharmaceutical companies. However, it would be key that the site be developed and maintained by an independent administration body which would be shielded from any influence by the pharmaceutical companies.

Again, I thank you very much for taking the time to read my suggestions. When you have the time, I would appreciate a response. Also, if any of these suggestions fall outside of your purview, I would appreciate your advising me as to a more appropriate department to send them to.

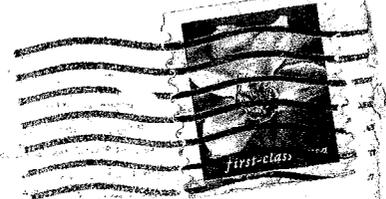
Sincerely,

A handwritten signature in black ink, appearing to read 'BJF' with a flourish extending to the right.

Brian J. Feldman, M.D.

BJF/dcn

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